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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,017	05/01/2001	Ta-Shuong Yeh	6230	5639

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/18/2003 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,017

Applicant(s)

YEH ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) ✓
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of amendments filed 1-7-03, 2-10-03, and 3-11-03 , revocation and power of attorney file 3-17-03 and request for extension of time (granted) filed 2-10-03 is acknowledged. Claims 1, 13, 18-20, and 22-23 have been amended as requested and new claims 34-62 have been added. It is noted in the amendment filed 3-11-03, Paper # 9, Applicant states that claims 1-61 are pending and makes no mention of claim 62. However, the amendment filed 2-10-03 added claim 62. Since the amendment of 3-11-03 did not cancel claim 62, it is still pending. Based upon the new grounds for rejection of claims requiring dibasic calcium phosphate, this action is "non-final."

Claim Objections

1. Claim 60 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 60 requires that the mixing is by tumble rotation, while claim 1, from which claim 60 depends, already requires that the mixing is by tumble rotation. Accordingly, claim 60 does not further limit claim 1.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1-10, 12-17, 22, 25, 31, 34-44, 47-52, 56-57 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774).**

6. '774 teaches a direct tableting auxiliary and method for its making comprising particles of microcrystalline cellulose and a binder such as polyvinylpyrrolidone (PVP) where the auxiliary is produced by heating ingredients that have an initial moisture

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content that is sufficient to moisten the ingredients but is insufficient to dissolve the binder completely in a fluidized bed (closed system). The size of the particles of '774 is within the instant range and the active agent is acetaminophen. The initial moisture content is provided either by water or an organic solvent such as ethanol and the K value for PVP is within the instant ranges. '774 does not specifically set forth initial moisture content within the instant range. However, '774 teaches that the initial moisture content is in an amount sufficient to moisten the ingredients but is insufficient to completely dissolve the binder.

Response to Arguments

7. Applicant's arguments filed 3-11-03 have been fully considered but they are not persuasive. Applicant argues that the instant process claimed (i.e. thermal adhesion granulation process) is different from the process of '774 in that the process of '774 requires a large amount of granulation fluid (i.e. water or organic solvent), while the instant claims are directed to an essentially dry process, arguing that the claimed processes specify that there is no more than a 20% initial moisture content while '774 teaches at least 41.9% initial moisture content. This argument is not found persuasive. The instant claims recite "...under the condition of from about 0.1 to about 20% initial moisture content **and/or** from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent." This allows for a total of 40% initial moisture content.

Applicant further argues that the instant process is different from '774 in that the process of '774 requires spraying of a mixture in an air stream to cause the particle to

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coalesce through impaction. These particles are then dried as the solvent is evaporated. Applicant argues that the thermal adhesion process claimed does not require these steps and is instead carried out by tumble rotation. It is the position of the Examiner that particles tumble and rotate in the airflow during fluidized bed granulation and the instant claims do not add additional steps.

Applicant then argues that the instant thermal adhesion granulation process occurs in a closed system, submitting that fluid bed granulation is not a closed system. This argument is not found persuasive. The instant specification provides no definition for a "closed system." Rudnic is cited of interest for showing various versions of fluidized-bed granulation systems. Each of the versions shows circulation of particles closed within a containment vessel.

8. **Claims 1-10, 12-27, 31-44, 47-57, and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in view of Hughes et al (6,350,751; hereafter '751).**

9. '774 is relied upon for all that it teaches as stated previously. '774 does not teach the inclusion of dibasic calcium phosphate anhydrous in the product/process.

10. '751 is relied upon for teaching inclusion of dibasic calcium phosphate anhydrous in tablet formulations as an excipient and PVP as a binder (see C 3, L 55-64; C 6, L 10-31).

11. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include dibasic calcium phosphate anhydrous in '774 as an excipient.

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12. **Claims 28-30 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in view of Ansel et al (1999).**

13. '774 is relied upon for all that it teaches as stated previously. It does not teach tablets in capsules.

14. Ansel teaches insertion of tablets into capsules to produce a formulation with a desired amount of active.

15. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine tablets into a capsule with the motivation of providing a single unit formulation having a particular desired dose.

16. **Claims 28-30 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in combination with Hughes et al (6,350,751; hereafter '751) and further in combination with Ansel et al (1999).**

17. '774 and '451 are relied upon for all that they teach as stated previously. Neither reference teaches tablets in capsules.

18. Ansel teaches insertion of tablets into capsules to produce a formulation with a desired amount of active.

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19. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine tablets into a capsule with the motivation of providing a single unit formulation having a particular desired dose.

20. **Claims 11 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al (EP 0 487 774; hereafter '774) in view of Rudnic (Remington, 1995).**

21. '774 is relied upon for all that it teaches as stated previously. '774 does not teach inclusion of crospovidone in the formulation.

22. Rudnic is relied upon for teaching inclusion of crospovidone in tablet formulations to facilitate breakup of the formulation.

23. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to include crospovidone in the formulation of '774 with the motivation of facilitating the disintegration of the formulation.

Response to Arguments

24. Applicant's arguments filed 3-11-03 have been fully considered but they are not persuasive. Applicant relies upon arguments in response to rejection of claims over Lang et al alone, arguing that Rudnic does not overcome the deficiencies of Lang. These arguments are addressed in paragraph 8, *supra*, and are again relied upon here.

Double Patenting

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25. Applicant is advised that should claim 61 be found allowable, claim 62 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).


Conclusion

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

tw
June 15, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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